

### **REMARKS**

In the Office Action dated April 19, 2004 (the "Final Office Action"), the Examiner has made final the rejection of claims 1, 2, 5-7 and 9-14 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,911,711 to Pelkey and the rejection of claims 3-4, 8 and 15 under 35 U.S.C. §103(a) as obvious over Pelkey in view of U.S. Patent No. 5,456,948 to Mathisen et al. New claim 30 has been added herein. The Examiner noted that the application contained claims 16-29 drawn to an invention nonelected with traverse; claims 16-29 have been cancelled herein. Entry of the amendment and favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

According to the Examiner, "the mixture of Pelkey would have the same properties as Applicant's." Applicants disagree. Pelkey describes his coatings in the summary of invention as follows: "The lubricious coating has a first layer formed from an at least partially cured organosiloxane copolymer and polydimethylsiloxane that has a viscosity greater than about 1000 centistokes. The lubricious coating has a second layer, applied as a secondary operation onto the first layer, that includes a polydimethylsiloxane having a viscosity between about 50 centistokes and about 350 centistokes." Pelkey goes on to describe his first coating as including "about four parts of a mixture of {50% solids (w/w)} dimethyl cyclosiloxane and dimethoxysilyldimethylaminopropyl silicone polymer in a mixture of mineral spirits and isopropyl alcohol (available from Dow-Corning, Midland, MI, as MDX 4-4159 fluid) and about two parts of polydimethylsiloxane (12,500 centistoke viscosity, available as DC-360 from Dow-Corning, Midland, Mich.)." (See Pelkey at column 3, lines 11-17.)

As set forth in the Material Safety Data Sheet for MDX4-4159 (a copy of which is attached hereto as Exhibit A), MDX4-4159 has a viscosity of 160 centistokes. It is respectfully submitted that, the Examiner's assertions notwithstanding, there is no evidence in Pelkey that its mixture of 4 parts of MDX4-4159, having a viscosity of only 160 centistokes, in combination with 2 parts of a polydimethylsiloxane having a viscosity of 12,500 would, in fact, inherently possess a viscosity of more than about 10,000 cP,

especially in view of the fact that the summary of invention describes “a first layer formed from an at least partially cured organosiloxane copolymer and polydimethylsiloxane that has a viscosity greater than about 1000 centistokes.” Moreover, as noted in applicant’s specification, its preferred polydimethylsiloxanes have “a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and preferably of at least about 30,000 cp. Such polydimethylsiloxanes for use herein include the products sold by Dow Corning under the name “Syl-Off DC 23”, which is suitable as a high density condensable polydimethylsiloxane, and NuSil Technology under the name “MED1-4162 (30,000cp).” (See Specification at page 6, lines 1-5.)

Thus, there is nothing in Pelkey to demonstrate Pelkey’s first coating would, in fact, have a viscosity of more than 10,000 cP as taught in Claim 1. The Examiner’s reliance upon applicant’s recitation of polydimethylsiloxane in a dependent claim as material which could be used in applicant’s composition to reject the independent claims is thus improper.

Moreover, nowhere does Pelkey disclose or suggest that its coating mixture may be utilized for surgical needles. The Examiner asserts the needles of Pelkey *could* be used during the course of surgery; however this argument fails to appreciate that the materials utilized in the coatings are not identical, as there is nothing to suggest Pelkey’s first coating would have a viscosity of 10,000 cP. Moreover, as previously pointed out by applicants, there is a difference between the use of a hypodermic needle, which is used either a single time or a very few times (e.g., for the administration of a local anesthetic) and thus has limited penetration in a patient, and the use of a surgical needle, which may be passed through a patient’s tissue numerous times to adequately close a wound.

With respect to applicant’s curing steps, the Examiner again fails to recognize the difference between the multiple coatings of Pelkey and applicant’s coatings. The Examiner describes in detail the different cure steps of Pelkey, for the different coatings, not recognizing the cure steps carried out by Applicant are for a single, mixed coating. Nowhere in Pelkey is there any teaching or suggestion to cure the compositions on its needles by “subjecting the coating mixture to an atmosphere of from about 20% to about

80% relative humidity, at a temperature from about 10° C. to about 50° C. for a time period ranging from about 1 hour to about 6 hours; and, heating the coating mixture to a temperature of from about 100° C. to about 200° C. for a time period ranging from about 2 hours to about 48 hours” as required by claims 10 and 11. Similarly, there is no teaching or suggestion in Pelkey to cure the compositions on its needles by “subjecting the coating mixture to an atmosphere of from about 50% to about 65% relative humidity, at a temperature from about 20° C. to about 35° C. for a time period ranging from about 2 hours to about 4 hours; and, heating the coating mixture to a temperature of from about 115° C. to about 150° C. for a time period ranging from about 15 hours to about 25 hours” as required by claims 12 and 13.

While the Examiner suggests one skilled in the art would have known the temperature and time to cure these materials, there is no support for this assertion. Pelkey’s “curing” steps are for the two different coatings. Thus, there is no teaching or suggestion in Pelkey for the parameters found in Applicants’ multiple stage curing process for the single mixture.

The Examiner has maintained the rejection of claims 3-4, 8 and 15 under 35 U.S.C. §103(a) as obvious over Pelkey in view of Mathisen et al., asserting that Mathisen was merely cited to disclose the use of hexane as a suitable solvent. However, as noted in response to the prior office action, without remedying the deficiencies of Pelkey noted above, Mathisen cannot be utilized to render claims 3-4, 8 and 15 obvious.

Applicants have also submitted herein a new independent claim, claim 30. It is respectfully submitted the new claim is patentable over the prior art cited by the Examiner and clearly supported by the specification (see page 8, line 17 to page 9, line 7).

It is believed that the claims of the application as now presented, i.e., claims 1-15 and 30, are patentably distinct over the art of record and are in condition for allowance.

Appl. No. 09/964,901  
Amdt. Dated June 21, 2004  
Reply to Office Action of April 19, 2004

In view of the foregoing amendment and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,



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**DOW CORNING**

# DOW CORNING CORPORATION

## Material Safety Data Sheet

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### DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION

#### 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Dow Corning Corporation  
South Saginaw Road  
Midland, Michigan 48686

**24 Hour Emergency Telephone: (989) 496-5900**  
Customer Service: (989) 496-6000  
Product Disposal Information: (989) 496-6315  
CHEMTREC: (800) 424-9300

MSDS No.: 01231367

Revision Date: 2002/01/18

Generic Description: Aminofunctional Siloxane  
Physical Form: Liquid  
Color: Straw  
Odor: Solvent odor.

NFPA Profile: Health 2 Flammability 3 Instability/Reactivity 0

Note: NFPA = National Fire Protection Association

#### 2. OSHA HAZARDOUS COMPONENTS

<u>CAS Number</u>	<u>Wt %</u>	<u>Component Name</u>
71750-81-7	40.0 - 70.0	Dimethoxysilyldimethyl aminoethyl aminopropyl silicone
8052-41-3	30.0 - 60.0	Stoddard solvent
67-63-0	15.0 - 40.0	Isopropyl alcohol
95-63-6	1.0 - 5.0	1,2,4-Trimethylbenzene
67-56-1	0.5 - 1.5	Methyl alcohol
541-02-6	0.1 - 1.0	Decamethylcyclopentasiloxane
108-67-8	0.1 - 1.0	1,3,5-Trimethylbenzene

The above components are hazardous as defined in 29 CFR 1910.1200.

#### 3. EFFECTS OF OVEREXPOSURE

##### Acute Effects

Eye: Direct contact may cause severe irritation.

Skin: May cause moderate irritation.

Inhalation: Vapor may irritate nose and throat. Vapor overexposure may cause drowsiness.

Oral: Overexposure by ingestion may cause effects similar to those listed under repeated exposure.

##### Prolonged/Repeated Exposure Effects

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**Skin:** Repeated or prolonged exposure may irritate seriously.

**Inhalation:** Product generates methyl alcohol which may cause blindness and damage to nervous system. Overexposure by inhalation may injure the following organ(s): Lungs. Liver. Kidneys. Nervous system.

**Oral:** Product generates methyl alcohol which may cause blindness and possibly death if swallowed.

##### Signs and Symptoms of Overexposure

No known applicable information.

##### Medical Conditions Aggravated by Exposure

No known applicable information.

The above listed potential effects of overexposure are based on actual data, results of studies performed upon similar compositions, component data and/or expert review of the product. Please refer to Section 11 for the detailed toxicology information.

#### **4. FIRST AID MEASURES**

**Eye:** Immediately flush with water for 15 minutes. Get medical attention.

**Skin:** Remove from skin and wash thoroughly with soap and water or waterless cleanser. Get medical attention if irritation or other ill effects develop or persist.

**Inhalation:** Remove to fresh air. Get medical attention if ill effects persist.

**Oral:** Get medical attention.

**Comments:** Treat same as methyl alcohol poisoning.

#### **5. FIRE FIGHTING MEASURES**

**Flash Point:** 55.9 °F / 13.3 °C (Pensky-Martens Closed Cup)

**Autoignition Temperature:** Not determined.

**Flammability Limits in Air:** Not determined.

**Extinguishing Media:** On large fires use dry chemical, foam or water spray. On small fires use carbon dioxide (CO<sub>2</sub>), dry chemical or water spray. Water can be used to cool fire exposed containers.

**Fire Fighting Measures:** Self-contained breathing apparatus and protective clothing should be worn in fighting large fires involving chemicals. Use water spray to keep fire exposed containers cool. Determine the need to evacuate or isolate the area according to your local emergency plan.

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### DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION

**Unusual Fire Hazards:** Vapors are heavier than air and may travel to a source of ignition and flash back. Static electricity will accumulate and may ignite vapors. Prevent a possible fire hazard by bonding and grounding or inert gas purge.

#### Hazardous Decomposition Products

Thermal breakdown of this product during fire or very high heat conditions may evolve the following hazardous decomposition products: Carbon oxides and traces of incompletely burned carbon compounds. Silicon dioxide. Formaldehyde.

### 6. ACCIDENTAL RELEASE MEASURES

**Containment/Clean up:** Remove possible ignition sources. Determine whether to evacuate or isolate the area according to your local emergency plan. Observe all personal protection equipment recommendations described in Sections 5 and 8. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Clean area as appropriate since some silicone materials, even in small quantities, may present a slip hazard. Final cleaning may require use of steam, solvents or detergents. Dispose of saturated absorbent or cleaning materials appropriately, since spontaneous heating may occur. Local, state and federal laws and regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which federal, state and local laws and regulations are applicable. Sections 13 and 15 of this MSDS provide information regarding certain federal and state requirements.

**Note:** See section 8 for Personal Protective Equipment for Spills. Call Dow Corning Corporation, (989) 496-5900, if additional information is required.

### 7. HANDLING AND STORAGE

Use with adequate ventilation. Product evolves flammable methyl alcohol when exposed to water or humid air. Provide ventilation during use to control exposure within Section 8 guidelines or use air-supplied or self-contained breathing apparatus. Avoid eye contact. Avoid skin contact. Do not breathe vapor. Keep container closed. Do not take internally.

Static electricity will accumulate and may ignite vapors. Prevent a possible fire hazard by bonding and grounding or inert gas purge. Keep container closed and away from heat, sparks, and flame. Keep container closed and store away from water or moisture.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Component Exposure Limits

<u>CAS Number</u>	<u>Component Name</u>	<u>Exposure Limits</u>
71750-81-7	Dimethoxysilyldimethyl aminoethyl aminopropyl silicone	See methyl alcohol comments.
8052-41-3	Stoddard solvent	OSHA PEL (final rule): TWA 500 ppm and ACGIH TLV: TWA 100 ppm.

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**DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION**

67-63-0 Isopropyl alcohol

OSHA PEL (final rule): TWA 400 ppm, 980 mg/m<sup>3</sup>.  
ACGIH TLV: TWA 400 ppm, STEL 500 ppm.

Methyl alcohol forms on contact with water or humid air. Provide adequate ventilation to control exposures within guidelines of OSHA PEL: TWA 200 ppm and ACGIH TLV-skin: TWA 200 ppm, STEL 250 ppm.

**Engineering Controls**

Local Ventilation: Recommended.  
General Ventilation: Recommended.

**Personal Protective Equipment for Routine Handling**

Eyes: Use chemical worker's goggles.

Skin: Wash at mealtime and end of shift. If skin contact occurs, change contaminated clothing as soon as possible and thoroughly flush affected areas with cool water. Chemical protective gloves are recommended.

Suitable Gloves: Silver Shield(R). 4H(R).

Inhalation: Use respiratory protection unless adequate local exhaust ventilation is provided or air sampling data show exposures are within recommended exposure guidelines. Industrial Hygiene Personnel can assist in judging the adequacy of existing engineering controls.

Suitable Respirator: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits as determined by air sampling or are unknown, appropriate respiratory protection should be worn. Follow OSHA Respirator Regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators.

**Personal Protective Equipment for Spills**

Eyes: Use full face respirator.

Skin: Wash at mealtime and end of shift. If skin contact occurs, change contaminated clothing as soon as possible and thoroughly flush affected areas with cool water. Chemical protective gloves are recommended.

Inhalation/Suitable Respirator: Respiratory protection recommended. Follow OSHA Respirator Regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Precautionary Measures: Avoid eye contact. Avoid skin contact. Do not breathe vapor. Keep container closed. Do not take internally. Use reasonable care.



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**DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION**

Comments: Product evolves flammable methyl alcohol when exposed to water or humid air. Provide ventilation during use to control exposure within Section 8 guidelines or use air-supplied or self-contained breathing apparatus.

Note: These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical Form: Liquid  
Color: Straw  
Odor: Solvent odor.  
Specific Gravity @ 25°C: 0.865  
Viscosity: 160 cSt  
Freezing/Melting Point: Not determined.  
Boiling Point: > 35C/95F  
Vapor Pressure @ 25°C: Not determined.  
Vapor Density: Not determined.  
Solubility in Water: Not determined.  
pH: Not determined.  
Volatile Content: Not determined.

Note: The above information is not intended for use in preparing product specifications. Contact Dow Corning before writing specifications.

**10. STABILITY AND REACTIVITY**

Chemical Stability: Stable.  
Hazardous Polymerization: Hazardous polymerization will not occur.  
Conditions to Avoid: None.  
Materials to Avoid: Oxidizing material can cause a reaction.

**11. TOXICOLOGICAL INFORMATION****Component Toxicology Information**

No known applicable information.

**Special Hazard Information on Components**

No known applicable information.

**12. ECOLOGICAL INFORMATION****Environmental Fate and Distribution**

Complete information is not yet available.

**DOW CORNING****DOW CORNING CORPORATION**  
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**DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION****Environmental Effects**

Complete information is not yet available.

**Fate and Effects in Waste Water Treatment Plants**

Complete information is not yet available.

**Ecotoxicity Classification Criteria**

Hazard Parameters (LC50 or EC50)	High	Medium	Low
Acute Aquatic Toxicity (mg/L)	<=1	>1 and <=100	>100
Acute Terrestrial Toxicity	<=100	>100 and <= 2000	>2000

This table is adapted from "Environmental Toxicology and Risk Assessment", ASTM STP 1179, p.34, 1993.

This table can be used to classify the ecotoxicity of this product when ecotoxicity data is listed above. Please read the other information presented in the section concerning the overall ecological safety of this material.

**13. DISPOSAL CONSIDERATIONS****RCRA Hazard Class (40 CFR 261)**

When a decision is made to discard this material, as received, is it classified as a hazardous waste? Yes

Characteristic Waste:

Ignitable: D001

State or local laws may impose additional regulatory requirements regarding disposal.

Call Dow Corning Corporate Environmental Management, (989) 496-6315, if additional information is required.

**14. TRANSPORT INFORMATION****DOT Road Shipment Information (49 CFR 172.101)**

Proper Shipping Name: FLAMMABLE LIQUID, N.O.S.

Hazard Technical Name: ISOPROPANOL/ALIPHATIC HYDROCARBONS

Hazard Class: 3

UN/NA Number: UN1993

Packing Group: II

**Ocean Shipment (IMDG)**

Proper Shipping Name: FLAMMABLE LIQUID, N.O.S.

Hazard Technical Name: ISOPROPANOL/ALIPHATIC HYDROCARBONS

Hazard Class: 3

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**DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION**

UN Number: 1993  
Packing Group: II  
Hazard Label(s): FLAMMABLE LIQUID  
Marine Pollutant: Not Applicable

**Air Shipment (IATA)**

Proper Shipping Name: FLAMMABLE LIQUID, N.O.S.  
Hazard Technical Name: ISOPROPANOL/ALIPHATIC HYDROCARBONS  
Hazard Class: 3  
UN Number: 1993  
Packing Group: II  
Hazard Label(s): FLAMMABLE LIQUID

Call Dow Corning Transportation, (989) 496-8577, if additional information is required.

**15. REGULATORY INFORMATION**

Contents of this MSDS comply with the OSHA Hazard Communication Standard 29 CFR 1910.1200.

TSCA Status: All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances.

**EPA SARA Title III Chemical Listings**

**Section 302 Extremely Hazardous Substances:**

None.

**Section 304 CERCLA Hazardous Substances:**

None.

**Section 312 Hazard Class:**

Acute: Yes  
Chronic: Yes  
Fire: Yes  
Pressure: No  
Reactive: No

**Section 313 Toxic Chemicals:**

<u>CAS Number</u>	<u>Wt %</u>	<u>Component Name</u>
67-63-0	15.0	Isopropyl alcohol

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95-63-6      1.0      1,2,4-Trimethylbenzene

**Supplemental State Compliance Information****California**

Warning: This product contains the following chemical(s) listed by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) as being known to cause cancer, birth defects or other reproductive harm.

None known.

**Massachusetts**

<u>CAS Number</u>	<u>Wt %</u>	<u>Component Name</u>
8052-41-3	30.0 - 60.0	Stoddard solvent
67-63-0	15.0 - 40.0	Isopropyl alcohol
95-63-6	1.0 - 5.0	1,2,4-Trimethylbenzene

**New Jersey**

<u>CAS Number</u>	<u>Wt %</u>	<u>Component Name</u>
71750-81-7	40.0 - 70.0	Dimethoxysilyldimethyl aminoethyl aminopropyl silicone
8052-41-3	30.0 - 60.0	Stoddard solvent
67-63-0	15.0 - 40.0	Isopropyl alcohol
95-63-6	1.0 - 5.0	1,2,4-Trimethylbenzene

**Pennsylvania**

<u>CAS Number</u>	<u>Wt %</u>	<u>Component Name</u>
71750-81-7	40.0 - 70.0	Dimethoxysilyldimethyl aminoethyl aminopropyl silicone
8052-41-3	30.0 - 60.0	Stoddard solvent
67-63-0	15.0 - 40.0	Isopropyl alcohol
95-63-6	1.0 - 5.0	1,2,4-Trimethylbenzene

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**DOW CORNING(R) MDX4-4159 50% MEDICAL GRADE DISPERSION**

**16. OTHER INFORMATION**

Prepared by: Dow Corning Corporation

These data are offered in good faith as typical values and not as product specifications. No warranty, either expressed or implied, is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

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